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030639-0027-UTL1
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Patent
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1614

In re the Application of:

Orville G. Kolterman, et al.

Serial No.: 09/889,330

International Application Filing Date: January
14, 2000

For: **NOVEL EXENDIN
FORMULATIONS AND METHODS OF
ADMINISTRATION THEREOF**

Group Art Unit: 1614

Examiner: To be assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In compliance with Applicants' duty under 37 CFR 1.56, the following information is brought to the attention of the Examiner. The items are listed on the attached form PTO/SB/08A and copies are enclosed for the convenience of the Examiner. Applicants respectfully request that an initialed copy of the PTO/SB/08A be returned with the next Communication.

It is believed that no fee is due for this submission since it is being filed before the mailing of a first Office Action on the merits. If, however, any fee should become due or credit become payable during the pendency of this application, the Patent Office is authorized to charge or credit the same to Deposit Account 50-1273.

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August 20, 2002
Date of Deposit

Laura Largey
Laura Largey

Respectfully submitted,
Kolterman et al.

Dated: August 19, 2002

By: Lisa M. McGeehan
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Reg. No. 41,185

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Sheet

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Application Number	09/889,330
Filing Date	January 14, 2000
First Named Inventor	Young
Art Unit	1614
Examiner Name	TBA

Attorney Docket
Number

030639.0027.UTL1

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)		
AA	5,424,286			06-13-1995	Eng

FOREIGN PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	Number ⁴ -Kind Code ⁵ (if known)		
AB	WO 97/46584			12-11-1997	Boehringer Mannheim GmgH
AC	WO 98/08871			03-05-1998	Novo Nordisk A/S
AD	WO 98/30231			07-16-1998	Amylin Pharmaceuticals, Inc.
AE	WO 99/07404			02-18-1999	Amylin Pharmaceuticals, Inc.
AF	WO 99/25727			05-27-1999	Amylin Pharmaceuticals, Inc.
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AH	WO 99/40788			08-19-1999	Amylin Pharmaceuticals, Inc.
AI	WO 99/43708			09-02-1999	Novo Nordisk A/S

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Sheet	3	of	4	Attorney Docket Number	030639.0027.UTL1
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		GLP-1 Analogs," <i>Diabetes</i> , 45(Suppl. 2):152A (1996) [abstract 553]	
AU	•	O'HALLORAN et al., "Glucagon-like Peptide-1 (7-36)-NH ₂ : a Physiological Inhibitor of Gastric Acid Secretion in Man," <i>J. Endocrinol.</i> , 126(1):169-73 (1990)	
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AW	•	RAUFMAN et al., "Exendin-3, a Novel Peptide from <i>Heloderma horridum</i> Venom, Interacts with Vasoactive Intestinal Peptide Receptors and a Newly Described Receptor on Dispersed Acini from Guinea Pig Pancreas," <i>J. Biol. Chem.</i> , 266(5):2897-902 (1991)	
AX	✓	RAUFMAN et al., "Truncated Glucagon-like Peptide-1 Interacts with Exendin Receptors in Dispersed Acini from Guinea Pig Pancreas", <i>J. Biol. Chem.</i> 267(30):21432-37 (1992)	
AY	✓	SCHEPP et al., "Exendin-4 and Exendin-(9-39)NH ₂ : Agonist and Antagonist, Respectively, at the Rat Parietal Cell Receptor for Glucagon-like Peptide-1-(7-36)NH ₂ ," <i>Eur. J. Pharm.</i> , 269:183-91 (1994)	
AZ	•	SCHJOLDAGER et al., "GLP-1 (Glucagon-like Peptide 1) and Truncated GLP-1, Fragments of Human Proglucagon, Inhibit Gastric Acid Secretion in Humans," <i>Digest. Dis. Sci.</i> , 34(5):703-8 (1989)	
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BB		THORENS et al., "Cloning and Functional Expression of the Human Islet GLP-1 Receptor," <i>Diabetes</i> , 42(11):1678-82 (1993)	
BC	•	THORENS, "Expression Cloning of the Pancreatic β Cell Receptor for the Glucocincretin Hormone Glucagon-like Peptide 1," <i>P. Natl. Acad. Sci. USA</i> , 89:8641-45 (1992)	
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BE	✓	WANG et al., "Glucagon-like Peptide-1 Is a Physiological Incretin in Rat," <i>J. Clin. Invest.</i> , 95:417-21 (1995)	

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	BF	WETTERGREN et al., "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and Pancreatic Functions in Man," <u>Digest. Dis. Sci.</u> , 38(4):665-73 (1993)	
	BG	WILLMS et al., "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," <u>J. Clin. Endocrinol. Metab.</u> , 81(1):327-32 (1996)	

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OTHER PRIOR ART, NON-PATENT LITERATURE DOCUMENTS

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	AJ	BHAVSAR et al., "Inhibition of Gastric Emptying and of Food Intake Appear to be Independently Controlled in Rodents," 25 th Annual Meeting, November 11-16, 1995, San Diego, California, <u>Soc. Neurosci.</u> , 21:460 (Abstract) (188.8) (1995)		
	AK	D'ALESSIO et al., "Elimination of the Action of Glucagon-like Peptide 1 Causes an Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons," <u>J. Clin. Invest.</u> , 97(1):133-38 (1996)		
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	AN	ENG, "Prolonged Effect of Exendin-4 on Hyperglycemia of db/db Mice," <u>Diabetes</u> , 45(Supp 2):152A (abstract 554) (1996)		
	AO	ENG et al., "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom," <u>J. Biol. Chem.</u> , 265(33):20259-62 (1990)		
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	AR	GOKE et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting β -Cells," <u>J. Biol. Chem.</u> , 268(26):19650-55 (1993)		
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	AT	MONTROSE-RAFIZADEH et al., "Structure-function Analysis of Exendin-4 /		

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